

WHAT IS CLAIMED:

1. A system for enabling at least one operator to control the delivery of an embolic protection device to a position in a patient's vasculature distal to an interventional procedure site for deployment of the embolic protection device, to enable the operator to control the removal of the delivery system from the patient's vasculature for the exchange of the delivery system, and to enable control of the position of a deployed embolic protection device within the patient's vasculature during an exchange of interventional devices, comprising:

a guide wire, including a distal end, adapted to be positioned within the blood vessel and to extend to a position distal to the interventional procedure site, and to include an embolic protection device mounted on the distal end thereof; and

a catheter, including a distal end, wherein the catheter has a lumen therein extending in the catheter to the distal end thereof, and wherein the guide wire and the embolic protection device are adapted to extend in and through the lumen, the catheter and the guide wire are adapted to enable the embolic protection device to be delivered and deployed distal to the interventional procedure site, and the catheter includes a manipulation-enabling element for enabling at least one operator to manipulate the guide wire and the catheter independently so as to enable removal of the catheter from the patient's vasculature.

2. The system of claim 1, wherein the catheter further includes a mandrel extending therein, adapted to support the catheter, to enable the catheter to maintain a clinically acceptable profile and flexibility during delivery and removal thereof through the patient's vasculature.

3. The system of claim 1, wherein the catheter includes a tip, at the distal end thereof, adapted to be shapeable by the operator, to enable the operator to direct the shapeable tip for movement thereof in the patient's vasculature.

4. The system of claim 1, further comprising a system for enabling the at least one operator to control the recovery of the embolic protection device, from the delivered and deployed position thereof, for the exchange of the recovery system.

5. The system of claim 2, wherein the manipulation-enabling element comprises a projection proximate the distal end of the catheter, adapted to communicate with the lumen, and to enable a minor portion of the guide wire to extend in the lumen, and a major portion of the guide wire to extend outside the catheter therethrough.

6. The system of claim 2, wherein the catheter includes a distal end portion, extending from the distal end to a location spaced from the distal end, a proximal end, and a distal-proximal portion, extending from the distal end portion to the proximal end, and the manipulation-enabling element extends along the distal-proximal portion of the catheter.

7. The system of claim 4, wherein the recovery system includes the catheter, and the distal end of the catheter includes a tip, adapted to be shapeable by the operator, to enable the operator to direct the shapeable tip for movement thereof in the patient's vasculature, and wherein the shapeable tip is further adapted to be expandable to enable the capture of the embolic protection device.

8. The system of claim 5, wherein the projection is adapted to enable the catheter and the guide wire to be manipulated by the operator.

9. The system of claim 5, wherein the catheter comprises an inner catheter, and the system further comprises an outer catheter, adapted to extend about the inner catheter and to be extendable in the distal direction by the operator so as to enclose the embolic protection device for enabling recovery thereof.

10. The system of claim 6, wherein the manipulation-enabling element is adapted to enable the guide wire to be peeled away from and extend outside the catheter and along the distal-proximal portion thereof.

11. The system of claim 6, wherein the manipulation-enabling element comprises a slit extending along the distal-proximal portion of the catheter.

12. The system of claim 10, wherein the manipulation-enabling element is adapted to enable a minor portion of the guide wire to extend in the lumen, and a major portion of the guide wire to extend outside the catheter therethrough.

13. The system of claim 11, wherein the slit is adapted to enable the catheter and the guide wire to be manipulated by the operator, so as to enable the guide wire to exit from and extend therethrough, and outside and along the distal-proximal portion of the catheter.

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16. The system of claim 15, wherein the delivery sheath includes a tip at the distal end thereof, adapted to be necked for providing a profile close to the guide

wire, to inhibit kinking of the guide wire during the delivery and removal of the delivery sheath.

17. The system of claim 15, wherein the delivery sheath includes a main shaft, adapted to provide the low profile, flexibility, and rigidity.

18. The system of claim 15, further comprising a system for enabling the recovery of the embolic protection device from the position in the patient's vasculature distal to the interventional procedure site, for removal of the embolic protection device, wherein the recovery system is adapted to maintain a clinically acceptable profile and flexibility during the delivery and removal of the recovery system through the patient's vasculature, and wherein the recovery system includes an inner catheter, including a distal end, wherein the inner catheter has a lumen therein extending in the inner catheter to the distal end thereof, and wherein the inner catheter is adapted to extend over the guide wire, and the distal end of the inner catheter is adapted to be positionable adjacent the embolic protection device, and wherein the inner catheter comprises dimensions and materials adapted to enable a smooth transition for movement thereof along the guide wire, to inhibit kinking of the guide wire during the delivery and removal of the inner catheter, and to maintain a clinically acceptable profile and flexibility during the delivery and removal thereof through the patient's vasculature.

19. The system of claim 16, wherein the tip of the delivery sheath is comprised of material adapted to be soft, to inhibit trauma to the patient's vasculature.

20. The system of claim 17, wherein the main shaft of the delivery sheath is comprised of PeBax, of about 72 Durometer.

21. The system of claim 18, wherein the recovery system further includes an outer catheter, including a distal end, wherein the outer catheter has a lumen therein extending in the outer catheter to the distal end thereof, the outer catheter is adapted to extend over the inner catheter, and the outer catheter comprises  
5 dimensions and materials adapted to enable a smooth transition for movement thereof along the inner catheter, to enable the capturing of the embolic protection device, and to inhibit trauma to the patient's vasculature, so as to maintain a clinically acceptable profile and flexibility during the delivery and removal thereof through the patient's vasculature.

22. The system of claim 19, wherein the tip of the delivery sheath is comprised of a compound including PeBax, of about 40 Durometer, and bismuth.

23. The system of claim 21, wherein the outer catheter includes a main shaft, adapted to enable the smooth transition, and to inhibit trauma.

24. The system of claim 21, wherein the outer catheter includes a distal end, and a tip at the distal end, adapted to enable the smooth transition, and to capture the embolic protection device, and comprised of material adapted to be soft, to inhibit trauma to the patient's vasculature.

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25. The system of claim 23, wherein the main shaft of the outer catheter is comprised of a high density PE.

26. The system of claim 24, wherein the tip of the outer catheter is comprised of a compound including PeBax, of about 40 Durometer, and bismuth.

27. A method of enabling at least one operator to control the delivery of an embolic protection device to a position in a patient's vasculature distal to an interventional procedure site for deployment of the embolic protection device, to enable the operator to control the removal of the delivery system from the patient's vasculature for the exchange of the delivery system, and to enable control of the position of a deployed embolic protection device within the patient's vasculature during an exchange of interventional devices, in a system which comprises a guide wire, including a distal end, adapted to be positioned within the blood vessel and to extend to a position distal to the interventional procedure site, and to include an embolic protection device mounted on the distal end thereof, and a catheter, including a distal end, wherein the catheter has a lumen therein extending in the catheter to the distal end thereof, and wherein the guide wire and the embolic protection device are adapted to extend in and through the lumen, the catheter and the guide wire are adapted to enable the embolic protection device to be delivered and deployed distal to the interventional procedure site, and the catheter includes a manipulation-enabling element for enabling at least one operator to manipulate the guide wire and the catheter independently so as to enable removal of the catheter from the patient's vasculature, wherein the method comprises:

the at least one operator:

inserting the guide wire with the embolic protection device mounted on the distal end thereof and the catheter into the blood vessel to the position distal to the interventional procedure site;

- 5       deploying the embolic protection device at the position thereof distal to the interventional procedure site;

detaching the catheter from the embolic protection device; and

manipulating the guide wire and the catheter independently so as to control the removal of the catheter from the patient's vasculature.

28.     The method of claim 27, further comprising a system for enabling the at least one operator to control the recovery of the embolic protection device, from the delivered and deployed position thereof, for the exchange of the recovery system, further comprising inserting the catheter through the patient's vasculature to a position  
5       adjacent the embolic protection device, capturing the embolic protection device, and manipulating the guide wire and the catheter independently so as to control the removal of the catheter and the embolic protection device from the patient's vasculature.

29.     A method of enabling the delivery of an embolic protection device to a position in a patient's vasculature distal to an interventional procedure site, for deployment of the embolic protection device, in a delivery system which is adapted to maintain a clinically acceptable profile and flexibility during the delivery and removal  
5       thereof through the patient's vasculature, wherein the delivery system comprises a guide wire, including a distal end, adapted to be positioned within the blood vessel and to extend to a position distal to the interventional procedure site, and to include an embolic protection device mounted on the distal end thereof, and a delivery sheath, including a distal end, wherein the delivery sheath has a lumen therein extending in the

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delivery sheath to the distal end thereof, and wherein the guide wire and the embolic protection device are adapted to extend in and through the lumen, the delivery sheath and the guide wire are adapted to enable the embolic protection device to be delivered and deployed distal to the interventional procedure site, and the delivery sheath

- 5 comprises dimensions and materials adapted to provide a low profile, flexibility for enabling tracking thereof through the patient's vasculature, and rigidity for enabling pushing thereof through the patient's vasculature, so as to maintain a clinically acceptable profile and flexibility during the delivery and removal thereof through the patient's vasculature, and wherein the method comprises:

- 10 extending the guide wire with the embolic protection device mounted on the distal end thereof through the lumen in the delivery sheath such that the embolic protection device is positioned at the tip of the delivery sheath;

delivering the delivery sheath through the patient's vasculature, so as to enable delivery of the embolic protection device for deployment thereof at the position

- 15 distal to the interventional procedure site, including enabling the delivery sheath to maintain a clinically acceptable profile and flexibility during delivery thereof; and

removing the delivery sheath through the patient's vasculature, including enabling the delivery sheath to maintain a clinically acceptable profile and flexibility during removal thereof.

30. The method of claim 29, further comprising a system for enabling the recovery of the embolic protection device from the position in the patient's vasculature distal to the interventional procedure site, for removal of the embolic protection device, wherein the recovery system is adapted to maintain a clinically

5 acceptable profile and flexibility during the delivery and removal of the recovery system through the patient's vasculature, and wherein the recovery system includes an inner catheter, including a distal end, wherein the inner catheter has a lumen therein

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extending in the inner catheter to the distal end thereof, the inner catheter is adapted to extend over the guide wire, and the distal end of the inner catheter is adapted to be positionable adjacent the embolic protection device, and the inner catheter comprises dimensions adapted to enable a smooth transition for movement thereof along the guide wire, to inhibit kinking of the guide wire during the delivery and removal of the inner catheter, and to maintain a clinically acceptable profile and flexibility during the delivery and removal thereof through the patient's vasculature, further comprising delivering the inner catheter through the patient's vasculature to the position adjacent the proximal end of the embolic protection device, including maintaining a clinically acceptable profile and flexibility during delivery thereof.

31. The method of claim 30, wherein the recovery system further includes an outer catheter, including a distal end, wherein the outer catheter has a lumen therein extending in the outer catheter to the distal end thereof, the outer catheter is adapted to extend over the inner catheter, and the outer catheter comprises dimensions and materials adapted to enable a smooth transition for movement thereof along the inner catheter, to enable the capturing of the embolic protection device, and to inhibit trauma to the patient's vasculature, so as to maintain a clinically acceptable profile and flexibility during the delivery and removal thereof through the patient's vasculature, further comprising delivering the outer catheter through the patient's vasculature so as to extend along the inner catheter and enclose the embolic protection device therein, including maintaining a clinically acceptable profile and flexibility during delivery thereof, and removing the outer catheter through the patient's vasculature with the inner catheter and the embolic protection device enclosed therein, including maintaining a clinically acceptable profile and flexibility during removal thereof.